

§ 10.10

Secretary means the Secretary of Health and Human Services.

The laws administered by the Commissioner or the laws administered by the Food and Drug Administration means all the laws that the Commissioner is authorized to administer.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a center, the reference includes all persons to whom that person has delegated the specific function involved.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 8994, Mar. 6, 1985; 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994; 69 FR 17290, Apr. 2, 2004]

§ 10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§ 10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

21 CFR Ch. I (4–1–09 Edition)

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Division of Dockets Management; computation of time; availability for public disclosure.

(a) A submission to the Division of Dockets Management of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant FEDERAL REGISTER notice or in another section of this chapter. The Division of Dockets Management is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is:

- (i) A reported Federal court case;
- (ii) A Federal law or regulation;
- (iii) An FDA document that is routinely publicly available; or
- (iv) A recognized medical or scientific textbook that is readily available to the agency.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be accompanied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to